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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,588	04/17/2000	LARRY S. MILLSTEIN	LAMILL2	2048

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EXAMINER

FRIEND, TOMAS H F

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,588

Applicant(s)

MILLSTEIN, LARRY S.

Examiner

Tomas Friend

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-99 is/are pending in the application.
- 4a) Of the above claim(s) 79-93, 98 and 99 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 94 is/are allowed.
- 6) ☒ Claim(s) 48-55, 58-67, 69, 71, 77, 78 and 95-97 is/are rejected.
- 7) ☒ Claim(s) 56, 57, 68, 70 and 72-76 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Art Unit: 1627

Detailed Action

Change of Art Unit Designation

Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1627 to Art Unit 1639. To aid in matching papers to this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Change of Examiner's Name

The name of the examiner of this application has ~~changed from Thomas Prasthofer to~~ Tomas Friend.

Status of the Application

The request filed on 23 May 2002 (Paper No. 11) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/529,588 is acceptable and a CPA has been established. An action on the CPA follows. Receipt is acknowledged of a response to an office action with amendment 10 July 2002 (Paper No. 13).

Status of the Claims

Claims 48-93 were pending in the application. Claims 80-93 were withdrawn from further consideration in Paper No. 9. New claims 94-99 were added in Paper No. 13.

Newly submitted claims 79, 98 and 99 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are drawn to an array (or wafer), which corresponds to non-elected Group II (claims 80-93) rather than the elected method of making replicate arrays. Claim 79 has been amended to recite a "*method according to claim 71, further comprising exposing a sample to the array and detecting the presence of binding to the analyte binding reagents using radioactivity, fluorescence, phosphorescence, or chemiluminescence*" (i.e. an assay step) resulting in an assay method that

Art Unit: 1627

uses a product of the method of making replicate arrays (New Group III). Elected Group I is classified, for example, in class 435, digest 49, whereas new Group III is classified, for example, in class 435, and one of digests 9-19. The two methods are patentably distinct because they produce two different results. The method of Group I produces an array, whereas the method of Group III results in the detection of an analyte. Searching both Groups would be burdensome because the two Groups require different class and/or subclass (digest) and keyword searches, for example.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 98 and 99 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 48-78 and 94-97 are pending and examined on their merits.

Withdrawn Rejections and Objections

1. All outstanding rejections and objections are withdrawn in response to applicant's amendment and arguments.

Allowable Subject Matter

2. Claim 94 is allowed. Claims 56, 57, 68, 70, and 72-76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Objections to the Claims

3. Claim 63 is objected to because of the following informalities: a typographical error "...according to claims 48...". Appropriate correction is required.
4. Claim 57 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place it in proper dependent form, or rewrite the claim in independent form. It would appear that any surface shape other than planar will increase surface area. Consequently, it is not clear how claim 57 further limits claim 56.
5. Claims 56, 57, 68, 70, and 72-76 are objected to as being dependent upon a rejected base claim

New Grounds of Rejection

The statutory basis for each of the following rejections not found below may be found in a prior office action.

Claims Rejections – 35 U.S.C. 101 and 112, second paragraph

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 78 provides for the use of an array in an assay, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Art Unit: 1627

Claim 78 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

7. Claims 96, 97, 71, and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 96, it is not clear if any of the array members are a glass or if at least one array member must be a glass.

B. Claim 97 recites "*wherein said replicate arrays produced are effective for performing assays.*" The term "*effective*" is a relative term which renders the claim indefinite. The term "*effective*" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. One of ordinary skill in the art would not be able to determine what the applicant considers to be "*effective*" because no objective criteria for assessing "*effectiveness*" are provided.

New Grounds of Rejection - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 48-55, 58, 60-67, 71, 77, and 95-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Nichols et al. U.S. Patent No. 5,853,884 issued December 1998.

Art Unit: 1627

The Nichols et al. patent discloses a method for forming a hollow fiber bundle unit for insertion in to an assisted breathing device (abstract). Column 3, lines 3-44, discloses hollow fibers are drawn, filed with humectant, bundled, and coated. A rod or cable of fiber bundle is formed which can be sliced (i.e. sectioned) into wafers. The humectants used can include glycerol, polyols, and calcium chloride (all homogeneous compositions), for example. The humectants are also "*analyte binding reagents*" because they can and do bind to other molecules. The fibers and/or the binders disclosed in lines 16-25 can be considered to be alignment members. The binding material may also be considered "*embedded information*" in the broadest sense of the term, the information being the composition of the binding material. The hollow fibers may be made from polycarbonate or polysulfone, for example. Column 4, lines 30-36, disclose that the bundles may be cut cross-sectionally or transversely. Accordingly, present claims 48-55, 58, 60-62, 97, 71, 77, 95, and 96.

Column 4, lines 41-53, discloses bundles of 0.92 inches in diameter and fibers of 460 μm to 550 μm in diameter, anticipating present claims 63-67.

9. Claims 48, 49, 51-53, 55, 58, 59, 63-67, 69, 71, 77, 78, and 97 are rejected under 35 U.S.C. 102(e) as being anticipated by Beattie, U.S. Patent No. 5,843,767 issued December 1998.

Column 9, lines 60-67, discloses that two-dimensional hexagonal close packing nanochannel glass arrays are fabricated by inserting a glass rod (array member) into an inert glass tube (structural/alignment member). The pair is drawn under vacuum into a fine filament. Filaments are stacked, refused and redrawn. The packed array elements are wafered perpendicular to the direction of the channels, which are later formed by etching the glass inside the lumen of the inert glass tube. The wafers are 0.1 to 1.0 mm thick. The glass rod is a binding reagent because it can bind other molecules. The arrays produced typically contain 10^7 channels (rods before etching) with diameters of 450 nm and inter array member distances from center to center are 750 nm (0.75 micrometers). Accordingly, the Beattie et al. reference anticipates present claims 48, 49, 51-53, 55, 58, 59, 63-67, 69, 97, 71, 77, and 78.

Art Unit: 1627

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner works on a flexible schedule of four ten-hour days per week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
01 November 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER